Vaccine Development: From the Laboratory to the FDA

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Observations of a Recovering ex-CBER Reviewer

Subtitle:

Vaccine development mistakes I've seen and how to avoid them

Mistake #1

The "I'm a world famous research scientist – Product Development will be a piece of cake" mistake

- Product development differs in significant ways from product discovery (basic research) and requires a specific set of skills which are not necessarily part of the typical basic researcher skill-set.

⇨ Process development is a team sport. Assemble the appropriate experts early in the process.

Product Development Skills

- Ability to see the “big picture’ of product development, which incorporates scientific, manufacturing, testing (preclinical and clinical), regulatory and quality issues.
- Able to interface and coordinate the various disciplines involved: Scientists, clinicians, toxicologists, regulatory affairs and quality system specialists.
- Ability to work productively with a diverse team of experts. Product development is NOT a do-it-yourself project

Mistake #2

The "We're just getting started – it's too soon to worry about regulatory issues" mistake

- Regulatory issues are critical at all stages of product development. Mistakes made early can have long-lasting effects. Mistakes caught early can significantly shorten development time.

⇨ Integrate regulatory awareness into ALL your decision making processes. A senior RA expert should be one of your priority early hires.

Mistake #3

The "If I keep quite about it, the FDA probably won't notice" mistake

- The FDA will eventually notice, but usually not until you've spent a year and a few million dollars doing it wrong.
- Current FDA meeting procedures place a real premium on asking the hard questions early in the game.
- The FDA is structured to respond to proposals, not to provide you with a roadmap.

⇨ The FDA is your best consultant (and cheapest). Make good use of the expertise

Mistake #4

The "The FDA didn't say NO, so they must mean YES" mistake

- The FDA rarely gives a flat NO and rarely says "you must do this…" – instead they say "have you considered ….", "we suggest that you try….", "we need more information about…."
- ALWAYS respond to suggestions – even if the response is "we have evaluated that idea and, for the following reasons, don't think it will work in our situation".

⇨ Pay attention to what they say. They are often trying to provide some useful information.

Mistake #5

The "Clinical development is going great – we can catch up with the product development later " mistake

- If your clinical development outruns your product development you can get in trouble.
- Product development can rarely be rushed and usually takes longer than you had planned, so product issues need to be top priority from day one.

⇨ Don't build a wall between the clinicians and the product developers. Remember, this is meant to be a team effort.

SUMMARY

- Product development is hard work which requires careful planning, unique expertise, and constant monitoring. Plan on doing it right from Day 1.
- Make every effort to establish and maintain credibility with the FDA.
  - Complete and easily reviewable submissions
  - Clearly explained rationales for all requests
  - Prompt and thorough responses to requests for information
  - Tell it like it is!